

Remarks

Claims 14-17, 32, 36, 37, and 40-48 are pending in the application following entry of this Amendment. Claims 14-17 and 42-47 stand withdrawn. Claim 32 has been amended. Claims 33-35 have been canceled in this Amendment, and claims 1-13, 18-31, 38, and 39 were previously canceled. Claim 48 has been added. Claim 32 is the only independent claim pending and not withdrawn.

No new matter is added by the amendments made herein. Support for the amendments to the claims is found in the specification as follows.

The amendment to claim 32 merely makes explicit what was implicitly recited in claim 32, as originally submitted, namely that the antibody recited in the claim binds with MCT-1 protein.

Claim 48 merely specifies the amino acid sequence of MCT-1 as disclosed in the specification as filed, for example, at page 6, lines 25 and 26, and in Figure 5.

Each of the Examiner's objections or rejections is addressed below in the order they were presented in the Office Action.

Rejection Pursuant to 35 U.S.C. § 101

The Examiner rejects all of the pending, non-withdrawn claims pursuant to 35 U.S.C. § 101. In the Examiner's view, the antibody recited in these claims was not recognized as having a substantial utility as of the priority date of this application. The Examiner asserts that the additional work was required to "establish that the claimed invention had utility." The Applicant respectfully disagrees with this assessment.

As indicated in the Applicant's response to the previous Office Action, the published references by Levenson et al. and by Hsu et al. demonstrate the significance of MCT-1 protein. The Applicant respectfully contends that the Examiner misunderstands the significance of the Levenson and Hsu references. The Examiner appears to consider the Levenson and Hsu references as indicating that there was no specific, substantial, and credible utility for an MCT-1-

binding antibody as of the priority date of the present application, since both the Levenson and Hsu references were published after that priority date.

Applicants submitted the Levenson and Hsu references as evidence that subsequently-published work recognized the significance disclosed in the application as filed of MCT-1 protein. In view of the significance disclosed in the specification for MCT-1 (and subsequently confirmed by others, such as the authors of the Levenson and Hsu references), a skilled artisan would recognize the usefulness (i.e., utility) of an antibody that specifically binds with MCT-1 protein.

Even in the absence of the Levenson and Hsu references, a skilled artisan would appreciate from the specification alone the utility of antibodies which bind specifically with MCT-1 protein. As disclosed, for example at page 6, lines 17-19, the specification indicates that MCT-1 is overexpressed in T-cell tumor cells, and that MCT-1 protein can be detected using antibodies that bind specifically with MCT-1 (see, e.g., page 47, lines 9-23). Furthermore, the specification demonstrates that, as of the priority date, the Applicant had used anti-MCT-1 immune serum to demonstrate overexpression of MCT-1 protein in T-cell tumor cells, relative to PBL control cells (see the paragraph bridging pages 49 and 50). The Applicant respectfully contend that these disclosures in the specification demonstrate a specific, substantial, and credible utility for the anti-MCT-1 antibodies that are presently claimed.

Rejections Pursuant to 35 U.S.C. § 112, First Paragraph

The Examiner rejects all of the pending, non-withdrawn claims pursuant to the enablement requirement of 35 U.S.C. § 112, first paragraph. In the Examiner's view, the specification's purported failure to identify a suitable utility for the claimed antibodies as of the priority date of the application would preclude a skilled artisan from being enabled by the specification to make use of those antibodies. The Applicants believe that the information presented in connection with the Examiner's rejection pursuant to 35 U.S.C. § 101 is equally applicable to this rejection, and that this rejection should be withdrawn for the same reasons presented in connection with that rejection -- namely, that the specification explicitly discloses at least one specific, substantial, and credible utility for the claimed antibody.

The Applicant notes that claims 33-35 (directed to antibodies that bind with particular portions of MCT-1 protein) have been canceled. The Applicant believes that he is entitled to allowance of canceled claims 33-35, but has canceled these claims in order to remove from consideration the issue of whether claims directed to antibodies which bind a particular portion of MCT-1 protein are sufficiently enabled by the specification. The claims that remain pending following entry of this Amendment merely recite that the antibody binds with specificity to "MCT-1," rather to any particular portion of the protein.

The Applicant respectfully contends that the specification explicitly demonstrates the Applicant's preparation of such antibodies (see, e.g., page 47, lines 9-23). The Applicant furthermore respectfully contends that methods of generating antibodies that specifically bind with an isolate protein were well known as of 11 May 1998 (the priority date of this application).

The specification discloses the claimed product and a specific, substantial, and credible use for the product. As of the priority date, numerous methods for making the product were widely known. The Applicant respectfully contends that the enablement requirement of 35 U.S.C. § 112, first paragraph, requires nothing more. Reconsideration and withdrawal of the Examiner's rejection of the pending, non-withdrawn claims pursuant to the enablement requirement of 35 U.S.C. § 112, first paragraph, are respectfully requested.

Summary

The Applicants respectfully contend that each of claims 32, 36, 37, 40, 41, and 48 is in condition for allowance. The Examiner is requested to issue a Notice of Allowance at the earliest possible time.

Respectfully submitted,

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(Date)

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